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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,850	10/17/2003	David W. Burke	7404-558	9581

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EXAMINER
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WATTS, ALLISON LEIGH

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 11/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/687,850

Applicant(s)

BURKE ET AL.

Examiner

Allison L. Watts

Art Unit

1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☒ Claim(s) 1 and 6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 2/24/2005, 8/16/2005.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

***Specification***

1. The disclosure is objected to because of the following informalities:

The word "applitude" on page 14 is misspelled.

The word "recognise" on page 24 is misspelled.

The word "defineing" on page 48 is misspelled.

The device "A5" is missing from the phrase "Devices to the left of the line in FIG. 31 (devices A2, A4, B2, B4, B5, C2, C4, and C5)" on page 49, if the applicant intended for it to be included.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 is indefinite in that the phrase "maintaining the first pair of electrodes in an inoperative state upon the measuring the first response" is unclear as to the meaning of "upon," which could indicate either "during the act of" or "after." It will be assumed that the inventor is indicating "after."

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5. Claim 6 is indefinite in that the phrase “providing a pair of measurement electrodes” is unclear as to whether the pair of measurement electrodes refers to one of the first or second pairs of electrodes disclosed in claim 1, or to a separate and additional pair of electrodes. It will be assumed that the inventor is indicating providing an additional pair of electrodes.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-5 and 7-11 are rejected under 35 U.S.C. 102(e) as being anticipated by Neel et al.

8. As to claim 1, Neel et al discloses a test strip (10), comprising a capillary fill chamber (88) that extends along the length of the test strip from an intake opening (68) to a terminus (70), a first pair of electrodes (22 and 24) in operative communication with the chamber, and a second pair of electrodes (28 and 30) in operative communication with the chamber (Figures 1-3). Neel et al discloses a method of performing a measurement on a biological fluid in a test strip (Column

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10, lines 41-42), comprising: providing a test strip, dosing the test strip with a biological fluid that so that the fluid flows from the intake opening to the terminus (Column 14, lines 43-51), applying a first test signal to one of the first pair of electrodes and measuring a first response to the first test signal at the other of the first pair of electrodes (Column 14, lines 48-55), maintaining the first pair of electrodes in an inoperative state after measuring the first response (Column 14, lines 55-57), applying a second signal to one of the second pair of electrodes and measuring a second response to the second test signal at the other of the second pair of electrodes (Column 14, line 67 through Column 15, line 3), and performing a measurement on the biological fluid after measuring the first response (Column 15, lines 26-28).

9. As to claim 2, Neel et al discloses the measuring of the first response to the first test signal is indicative of contact between the first pair of electrodes and the biological fluid (Column 14, lines 48-51).

10. As to claim 3, Neel et al discloses measuring the first response to the first test signal to indicate contact of the first pair of electrodes and the fluid (Column 14, line 63 through Column 15, line 11).

11. As to claim 4, Neel et al discloses measuring the second response to the second test signal to indicate contact of the second pair of electrodes and the fluid (Column 14, lines 48-55).

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12. As to claim 5, Neel et al discloses performing a measurement on the biological fluid by applying a test signal to one of the first pair of electrodes (Column 15, lines 47-58).

13. As to claim 7, Neel et al discloses a test strip (10), comprising a capillary fill chamber (88) that extends along the length of the test strip from an intake opening (68) to a terminus (70), a first pair of electrodes (22 and 24) in operative communication with the chamber, and a second pair of electrodes (28 and 30) in operative communication with the chamber (Figures 1-3). Neel et al discloses a method of performing a measurement on a biological fluid in a test strip (Column 10, lines 41-42), comprising: providing a test strip, dosing the test strip with a biological fluid that so that the fluid flows from the intake opening to the terminus (Column 14, lines 43-51), determining when the fluid contacts the first electrodes (Column 4, lines 65 through Column 5, line 2), determining when the fluid contacts the second electrodes (Column 5, lines 2-8), determining fill time based on the first and second determining (Column 14, lines 55-65), and comparing the fill time to a predetermined value (Column 5, lines 8-11).

14. As to claims 8 and 9, Neel et al discloses indicating an error if the fill time exceeds a predetermined value (Column 15, lines 19-24).

15. As to claims 10 and 11, Neel et al discloses performing a measurement on the fluid if the fill time is less than a predetermined value (Column 15, lines 26-32).

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***Claim Rejections - 35 USC § 103***

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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19. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Neel et al in view of Feldman et al.

20. Neel et al is relied upon as discussed in the rejection under 35 USC 102(e) set forth above. Neel et al also discloses a test strip comprising a sample chamber for the blood sample and "at least four electrodes" for measuring at least one electrical characteristic (Column 1, lines 57-60).

21. Feldman et al discloses using multiple working electrodes (42, 44, and 46), along with counter electrodes, to form electrode pairs that are in operative communication with a sample chamber (26) on a base material (48) (Column, 49, lines 7-12). Neel et al discloses using multiple electrode pairs for the purpose of either testing a variety of analytes using a single sample (Column 48, lines 17-19), or improving the accuracy of measurement results (Figure 5, Column 48, lines 39-40).

22. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the apparatus of Neel et al by adding an additional pair of measurement electrodes, as taught by Feldman et al, because Feldman et al teaches that multiple electrode pairs may be used to increase the amount of measurements that may be made.

23. The Information Disclosure Statement (IDS) submitted 2/24/2005 has been considered by the examiner. However, due to the large amount of prior art submitted by the applicant in this IDS, the examiner requests applicant's assistance in determining the relevance of the prior art to the application.



***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Allison L. Watts whose telephone number is (571) 272-6640. The examiner can normally be reached on Monday through Friday, 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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ALW

November 3, 2006

A handwritten signature in black ink, appearing to read 'Nam Nguyen', with a stylized, flowing script.

NAM NGUYEN  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1700